UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,625	12/18/2001	Ian D. McRury	022956-71 (MIT-239)	3998

21125 7590 03/05/2004

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	5

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,625	Applicant(s) MCRURY ET AL.	
	Examiner Bradford C Pantuck	Art Unit 3731	

-- Th MAILING DATE of this communication appears on the cov r sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 4, 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *9-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 December 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/12-18-01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 20, drawn to a suture welder and method of use, classified in class 606, subclass 32.

II. Claims 9-19, drawn to a suture welder with a grasper, classified in class 606, subclass 148.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I is an invention generically used for welding sutures together, whereas Invention II includes a grasper.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ron Cahill on February 23, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8 and 20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 5, 7, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,488,690 to Morris et al. Regarding Claim 1, 7, and 20, Morris discloses a suture welding system [Column 2, lines 27-33] for fixedly attaching a first length of suture to a second length. Morris also discloses a method of using his welding system. Morris discloses an electrosurgical energy source [Column 3, lines 13-17: "power-supply"], a suture welding device (100) [see Fig. 1], a working end (distal end of device 100), and a suture contacting element (108). Morris discloses both unipolar and bipolar arrangements for his electrodes [Column 3, lines 10-13].

In his bipolar arrangement [Figure 1], he discloses a first electrode (first wire) electrically coupled to the power supply (a battery or other form of power) disposed on the contacting element (108) for providing electrical energy to the suture [Column 3, lines 10-29]. As a part of his bipolar configuration, Morris also discloses a second electrode (second wire) coupled to the battery, which provides a return energy path to the battery. Specifically, Morris describes a "pair of insulated wires" [Column 3, line 26]. Those of ordinary skill in the welding art know that a "bipolar" configuration refers to an arrangement in which current travels from one electrode to another as a part of a complete circuit. Suture is put in the gap between the two electrodes and two lengths are attached to each other [Column 2, lines 38-48]. Figures 1 and 2 show the suture in contact with the suture contacting element (108). Although the respective locations of the tips of the wires are not clear from the disclosure, the *suture is certainly capable of being placed between them*. Figure 1 shows the suture between two grasping members and it can be assumed that one wire is in each grasper.

3. Regarding Claim 5, Morris discloses sutures that are thermoplastics such as nylon [Column 1, lines 26-30]. Such materials are "polymer plastics."

4. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,277,117 to Tetzlaff et al. Regarding Claim 1, Tetzlaff discloses a welding device capable of welding suture having two electrodes (110/120), an energy source ("electrosurgical generator") [Column 6, lines 31-33], and a suture contacting

element [Column 1, lines 34-42]. His invention is intended for use in welding body tissue, but is certainly capable of welding suture as well.

5. Regarding Claims 3 and 4, Tetzlaff discloses two opposing faces ("prongs") having a variable gap between them. Each face has an electrode (110/120) on top of it [Figure 2; Column 2, lines 41-48; Column 7, lines 49-58]. Although the stop member (106) [see Fig. 4 especially] prevents the electrodes from touching each other, *lengths of suture are capable of being placed between the two electrode surfaces and held there*.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,342,359 to Rydell. Regarding Claim 1, Rydell discloses a system capable of welding suture having two electrodes (34/36) [Column 4, lines 65-66], an energy source ("energy source" – see Abstract), and a suture contacting element (distal end of device). His invention is intended for use in welding body tissue, but is certainly capable of welding suture as well. Rydell discloses a "bipolar" instrument, which means that one of the electrodes will provide electrical current and the other will provide for return of the current to the source when the two electrodes come in contact with each other.

7. Regarding Claim 2, Rydell's device uses radio frequency waves [Column 8, lines 1-10; Column 5, lines 58-60].

8. Regarding Claim 8, with reference to Figure 4B, Rydell's device has a piston (16) that slides and is able to engage suture positioned in the distal hollow of component

34. The piston slides from the position shown in Fig. 4A to the position shown in Fig. 4B [Column 5, lines 24-27].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,488,690 to Morris in view of U.S. Patent No. 4,052,988 to Doddi et al. Morris does not disclose making suture out of polydioxanone, but Doddi teaches that one ought to make suture for use in the body out of polydioxanone because it has many desirable properties, including strength, smoothness, and pliability. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Morris' suture out of polydioxanone because this material has many surgically desirable properties such as tensile strength and pliability, as taught by Doddi.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,669,705 to Westhaver et al.

U.S. Patent No. 6,358,271 B1 to Egan et al.

U.S. Patent No. 6,464,704 B2 to Schmaltz et al.

U.S. Patent No. 5,336,221 to Anderson

U.S. Patent No. 5,258,006 to Rydell et al.

U.S. Patent No. 6,423,088 B1 to Fenton, Jr.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
February 24, 2004

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700